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3 use and usability of custom-made orthopaedic shoes

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abstract

Objectives: To evaluate use of custom-made orthopaedic shoes (OS) and the association between use of OS and the most relevant factors of their usability.

Procedures: Over a six-month period, patients meeting the inclusion criteria were recruited by twelve orthopaedic shoe companies scattered throughout the Netherlands, and asked to complete a questionnaire composed of a pre-part and a post-part.

Patients: Patients with different pathologies were included in the study (n=339; response 67%). Mean age of the patients was 63 ± 15 years, and 38% were male.

Results: Three months after delivery, 81% of the patients used their OS frequently (4–7 days/week), 13% occasionally (1–3 days/week), and 6% did not use their OS. Associations were found between use and all measured factors of usability (p-values varied from <.001 to .028). Patients who used their OS more often had a more positive opinion regarding all factors of usability of OS.

Conclusions: All factors of usability of OS are relevant in relation to their use, and should be taken into account when prescribing and evaluating OS.

introduction

Custom-made orthopaedic shoes (OS) are used for a large variety of serious foot and/or ankle problems: for example, to prevent recurrence of foot ulcers, reduce plantar pressure, diminish pain in the feet or ankles during standing and walking, support foot deformities, enhance mobility, or provide stability[3,11,20]. OS are prescribed for patients with a wide range of pathologies, such as diabetes, rheumatoid arthritis, degenerative foot disorders, spasticity, and muscular diseases[20]. These patients do not fit standard off-the-shelf footwear. OS, including the insole, are completely individually designed and fabricated from a positive model cast from the patient's foot.

In order to be effective, OS must be used by those for whom they are prescribed. However, it has been frequently reported that patients do not use their OS[1,5-7,9,10,12,14,18,19]. Varying rates of non-use have been reported, ranging from 20% to 25% for first-time users[5,12] and from 4% to 19% for experienced users[1,6,7,9,10,14,18,19]. Generalization or comparison of the results of these studies is almost impossible for three general reasons. First, most studies have been performed in one specific group of patients, which is different from the diversity seen in clinical practice.

Second, follow-up times vary from three months to two years after supply of the first pair of OS. Third, and most important, use of OS has been defined in many different ways but mainly as in the following three main categories: frequent, occasional, and non-use. These categories have been analyzed using two main combinations (frequent + occasional use vs. non-use[9,12,19] or frequent use vs. occasional + non-use[5,7,10]), without any definitive rationale for the specific combination. Other studies define use in categories that are not clearly described and sometimes not mutually exclusive[1,14,18].

Use of OS has been associated with several factors of their usability. Usability is 'the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction, in a specified context of use' (International Organization for Standardization (ISO), 9241-11). Within the domains of usability stated, a more positive score on any of the following factors has been associated with a higher frequency of use of OS: benefits of OS with regard to walking capacities, wound healing, or pain reduction (domain effectiveness); comfort and ease of use, and the efficiency of the delivery process of OS (domain efficiency); and cosmetic appearance, and communication with

the medical specialist or orthopaedic shoe technician (domain satisfaction)[1,2,4-7,9,10,12-14,16-19,21,23,24]. However, only one study has been conducted in which the associations between use and factors of all domains of usability have been studied, and that was conducted only with patients with degenerative disorders of the foot[12]. The focus of other studies has been on some factors of one or two domains of usability and often in one specific group of patients only[1,2,4-7,9,10,13,14,16-19,21,23,24].

The aim of the present study was to investigate use of OS in a group of patients that reflects the diversity seen in clinical practice, and to investigate the associations between use of OS and the most relevant factors of their usability.

methods

Procedures

A prospective cohort study with internal comparison was conducted. Over a six-month period, patients meeting the inclusion criteria were recruited by twelve orthopaedic shoe companies scattered throughout the Netherlands. A specially developed questionnaire comprising a pre-part and a post-part was used. After patients had given written informed consent, during the visit at which foot measurements were taken, the orthopaedic shoe technician gave the pre-part to the patients. These patients' personal data were sent to the researchers. The pre-part had to be completed and returned to the researchers before actual delivery of the OS. Three months after delivery of the OS, the researchers sent the post-part of the questionnaire to all patients who had previously completed the pre-part. However, in the current article, only analysis of the data acquired from the post-part of the questionnaire is presented.

Patients who did not complete either the pre-part or the post-part of the questionnaire within a month were contacted once by telephone by the researchers, in order to ask for the reason of the delay and possible problems, and were asked to complete the questionnaire.

Patients

A series of patients who were provided with their first-ever pair of OS by twelve Dutch orthopaedic shoe companies was included. Patients who were previous users of OS were excluded because large differences exist between first-time and experienced users[7]. Other inclusion criteria were (i) 16 years of age or older, (ii) able to read Dutch, and (iii) able to complete the questionnaire without help related to cognitive or physical

impairments.

The patient flow is shown in Figure 1. Mean age of the 339 patients included in the study was 63 ± 15 years, and 38% (n=129) were male. Of these patients, 85 had diabetes mellitus, 60 rheumatoid arthritis, 237 a foot disorder, 23 a muscular disease, and 104 another pathology (e.g., cerebral vascular accident, spinal cord injury, psoriasis, leather allergy, and others). Pathologies were indicated by patient self-report, and it was possible to indicate more than one pathology. The age and sex of the patients included in the study were comparable with the non-responders (patients who gave written informed consent but did not complete both

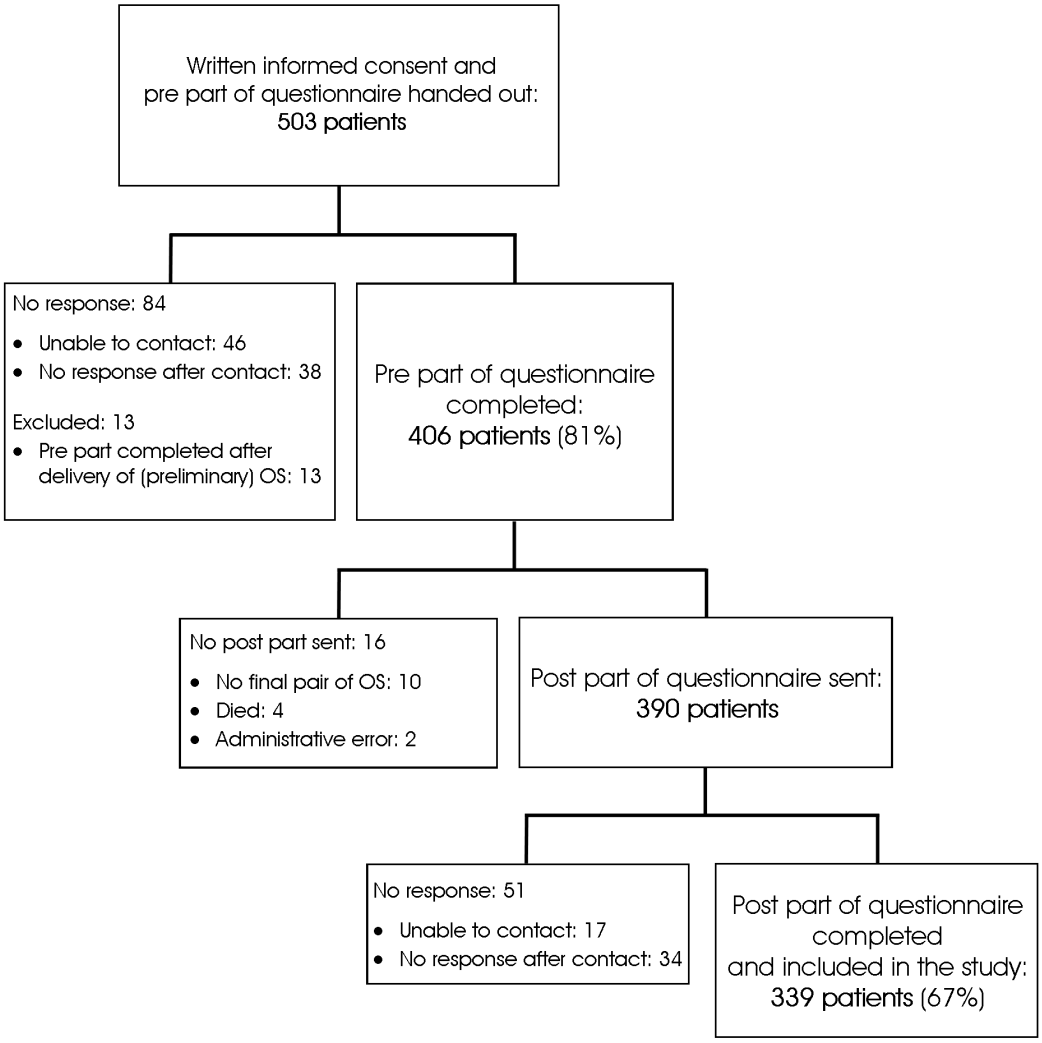

Figure 1: Patient flow

Note: OS = custom-made orthopaedic shoes.

sections of the questionnaire; mean age 59 ± 17 years and 41% male) and with all patients of the twelve orthopaedic shoe companies to whom a first-ever pair of OS was provided between January and June 2007 (data obtained via administration system of the orthopaedic shoe companies; mean age 63 ± 17 years and 39% male).

We were able to contact 34 of the 51 patients who did not respond to the post-part of the questionnaire. Reasons indicated for not responding were lack of interest (n=15), lack of time (n=10), not using OS and dissatisfied (n=3), not using OS because of change in medical situation (n=2), questionnaire missing in post (n=2), and no reason specified (n=2).

Outcome measures

We used the Monitor Orthopaedic Shoes (MOS), which is a practical and reproducible questionnaire that can be used for a wide range of patients[22]. The MOS consists of a pre-part and a post-part. For the purposes of this study, we used only the post-part, which was designed to measure use and the most relevant factors of usability of OS from a patient's perspective through multiple choice and visual analogue scale questions[22].

We defined three categories of use of OS: frequent use (4–7 days/week), occasional use (1–3 days/week), and non-use (not using OS). We further asked patients to indicate the average daily duration of use in hours. Use of OS was not specified into activities during which OS were used or location of use (e.g. indoor vs. outdoor).

Within the domains of usability as defined by the ISO, the following factors were measured: change in walking capacity, wound healing, change in pain, and change in sprains (domain effectiveness); donning and doffing OS, fit of OS, ease of walking with OS, and weight of OS (domain efficiency); cosmetic appearance, and communication with medical specialist and orthopaedic shoe technician (domain satisfaction).

Statistical analysis

We assessed differences between the three groups with a Kruskal-Wallis test. We used this test because of non-normal distribution of the data. We performed post hoc analyses to assess differences between the groups separately. We used a Chi-square test for categorical variables and calculated the effect size with Cramér's V. We used a Mann-Whitney U-test for scale measures with a non-normal distribution of the data and calculated the effect size with the formula (effect size = $Z / (n1 + n2)^8$). We

analyzed data using SPSS for Windows, version 16.0 (SPSS Inc; Chicago, Illinois).

results

Three months after delivery of OS, 81% (n=275) of the patients used OS frequently (4–7 days/week), 13% (n=43) used OS occasionally (1–3 days/week), and 6% (n=21) did not use OS. No significant differences were found between the patient characteristics of the three groups (Table 1). Patients who use their OS frequently have a significantly higher daily duration of use than patients who use them occasionally (Table 1).

The associations between use of OS and patients' opinions with regard to factors of usability of OS are shown in Table 2. Significant differences between the three groups were found for all factors of usability of

Table 1: Patient characteristics, categorized with regard to the frequency of use of their custom-made orthopaedic shoes three months after delivery

		Frequent use (81%; n=275)	Occasional use (13%; n=43)	Non use (6%; n=21)	p*
Age (years)	mean ± SD	63 ± 14	63 ± 17	63 ± 12	.998
Gender	Male	40% (110)	37% (16)	14% (3)	.061
	Female	60% (165)	63% (27)	86% (18)	
Main reason†	Pain	54% (147)	70% (30)	57% (12)	NA§
	Wounds	9% (25)	2% (1)	0% (0)	
	Foot deviation	23% (62)	12% (5)	19% (4)	
	Leg length difference	3% (7)	0% (0)	10% (2)	
	Other	12% (34)	16% (7)	14% (3)	
General health‡	Improved	19% (51)	7% (3)	29% (6)	NA§
	No change	71% (194)	79% (34)	52% (11)	
	Deteriorated	10% (28)	12% (5)	14% (3)	
	Missing	1% (2)	2% (1)	5% (1)	
Daily duration of use (hours/day)	>12 hours	24% (65)	5% (2)	NA	<.001ζ
	8 – 12 hours	34% (93)	2% (1)		
	4 – 8 hours	30% (83)	33% (14)		
	1 – 4 hours	11% (29)	47% (20)		
	< 1 hour	1% (1)	14% (6)		
	Missing	1% (4)	0% (0)		

Note: Values are % (n) or as indicated. Percentages may not add to 100 due to rounding. NA = not applicable. Frequent use = using custom-made orthopaedic shoes (OS) 4-7 days/week; Occasional use = using OS 1-3 days/week; Non use = not using OS. *: The p-value for the differences between the three groups on that factor is shown. †: The main reason was indicated by patients themselves. ‡: General health refers to the change in general health (not the feet specifically) between pre and post measurements. §: A Chi-square test was not applicable because more than 25% of the cells had an expected count less than 5. ζ: The p-value for the difference between frequent and occasional users only is shown, as this was not applicable for non users.

Table 2: Association between use of custom-made orthopaedic shoes and factors of their usability within the domains effectiveness, efficiency, and satisfaction

		Frequent use (81%; n=275)	Occasional use (13%; n=43)	Non use (6%; n=21)	p*
Effectiveness					
Walking capacity					
Improved, because of OS		76% (208)	33% (14)	0% (0)	
Improved, not because of OS		1% (3)	5% (2)	33% (7)	
No change		14% (39)	47% (20)	33% (7)	NA†
Deteriorated, not because of OS		7% (18)	9% (4)	0% (0)	
Deteriorated, because of OS		2% (4)	2% (1)	19% (4)	
Missing		1% (3)	5% (2)	14% (3)	
Wounds after OS‡					
(wounds before OS: n=49; 10; 0)	More	4% (2)	10% (1)	-	NA†
	Same	27% (13)	20% (2)	-	
	Less	22% (11)	20% (2)	-	
	Healed	47% (23)	50% (5)	-	
(no wounds before OS: n=226; 33; 21)	Wounds	6% (13)	6% (2)	0% (0)	NA†
	No wounds	94% (212)	94% (31)	71% (15)	
	Missing	0.5% (1)	0% (0)	29% (6)	
Change in pain (skin)§		82	66	22.5	<.001
(n=166; 25; 8)‡		(58.5 ; 95)	(28.5 ; 89.5)	(7.5 ; 46)	
Change in pain (muscles)§		79.5	58	20	<.001
(n=212; 33; 9)‡		(60 ; 92)	(35 ; 79.5)	(8 ; 48)	
Change in sprains§		92	83	45.5	.013
(n=147; 23; 4)‡		(75 ; 97)	(50 ; 96)	(31.25 ; 78.75)	
Efficiency					
Donning / doffing OS§		75 (49.5 ; 89)	63 (27.5 ; 79.5)	51.5 (15.75 ; 94.5)	.017
Weight of OS§		48 (27 ; 52)	26.5 (8.5 ; 49.25)	17 (6.75 ; 36.25)	<.001
Fit of OS§		84 (68 ; 95)	74 (38 ; 89)	64 (36 ; 89.5)	.002
Ease of walking with OS§		80 (62.25 ; 92)	52 (31 ; 81.5)	5 (4 ; 17.5)	<.001
Satisfaction					
Cosmetic appearance (patient)§		58 (46 ; 80)	49 (17 ; 87)	16 (2.5 ; 50.25)	<.001
Cosmetic appearance (others)ζ					
Ugly or very ugly		8% (22)	19% (8)	38% (8)	<.001
Neutral		37% (102)	47% (20)	19% (4)	
Attractive or very attractive		40% (110)	19% (8)	10% (2)	
Do not know or missing		15% (41)	16% (7)	33% (7)	
Communication with MS§		85 (67.25 ; 94)	79 (50 ; 88)	53.5 (17 ; 97.25)	.028
Communication with OST§		87 (64 ; 94.75)	78 (41 ; 90)	64 (15.5 ; 96.25)	.001

Note: Values are % (n) or Median (IQR). Percentages may not add up to 100 due to rounding. NA = not applicable; MS = Medical Specialist; OS = custom-made orthopaedic shoes; OST = orthopaedic shoe technician. Frequent use = using OS 4-7 days/week; Occasional use = using OS 1-3 days/week; Non use = not using OS. *: The p-value for the differences between the three groups on that factor is shown. †: A Chi-square test was not applicable because more than 25% of the cells had an expected count less than 5. ‡: Not all patients had wounds, pain or sprains, therefore the number of patients for these questions is indicated, for each group respectively. §: Scores could range from 0 (most negative score possible) to 100 (most positive score possible). ζ: Patients' answer on the question what others think about the cosmetic appearance of their OS.

OS, with a more positive score for patients who use their OS more often. The observations also indicate that more improvement was noted with regard to walking capacity in patients who frequently use their OS and that no differences were found with regard to wound healing, although a p-value could not be calculated for these factors

Results of the post-hoc analyses are shown in Table 3. Change in pain (both in the skin and in the muscles) and ease of walking with OS differed significantly between all groups. Both factors of cosmetic appearance (patient's opinion and opinion of others) differed significantly between patients who frequently use their OS and both other groups and approached significance between patients who occasionally use and those who do not use their OS. The largest effect sizes were found for ease of walking with OS and change in pain in the muscles. Finally, a significant effect for gender was found: compared with patients who frequently use their OS, significantly more female patients did not use their OS. Because of this gender effect, two more post-hoc analyses were performed. First, the associations between use of OS and factors of their usability were also calculated for the three groups of patients matched for gender. The results were the same: significant differences were found between the three groups for all factors of usability (results not shown).

Table 3: Post-hoc analyses on the significant main effects of frequency of use of custom-made orthopaedic shoes in domains of their usability

	Freq. – Non.		Freq. – Occ.		Occ. – Non.	
	p*	ES	p*	ES	p*	ES
Effectiveness						
Change in pain (skin)	<.001	.31	.027	.16	.010	.45
Change in pain (muscles)	<.001	.26	<.001	.23	.013	.38
Change in sprains	.013	.20	.081	.13	.109	.31
Efficiency						
Donning / doffing OS	.145	.09	.010	.15	.974	.00
Weight of OS	.001	.22	<.001	.20	.313	.13
Fit of OS	.035	.12	.003	.17	.831	.03
Ease of walking with OS	<.001	.36	<.001	.22	<.001	.59
Satisfaction						
Cosmetic appearance (patient)	<.001	.22	.003	.17	.079	.23
Cosmetic appearance (others)†	<.001	.34	.004	.20	.066	.33
Communication with MS	.094	.11	.025	.13	.464	.10
Communication with OST	.030	.13	.001	.18	.613	.06
Patient characteristics						
Gender‡	.019	.14	.728	.02	.059	.24

Note: Non-significant results for the patient characteristics 'age', 'main reason', and 'general health' are not shown. ES = effect size; MS = Medical Specialist; OS = custom-made orthopaedic shoes; OST = orthopaedic shoe technician. Freq. = Frequent use = using OS 4-7 days/week; Occ. = Occasional use = using OS 1-3 days/week; Non. = Non use = not using OS. *: The p-value for the difference between the groups is shown; a significant difference indicates that patients who use their OS more often have a significant more positive opinion with regard to that aspect. †: Patients' answer on the question what others think about the cosmetic appearance of their OS. ‡: A significant p-value indicates that men use their OS more frequent than women.

Second, gender differences were calculated for all factors of usability within the group of patients who frequently use their OS. No significant differences were found between the opinion of men and women on any of the factors of usability (results not shown).

discussion

In the present study, we found that three months after delivery, 81% of the patients used their OS frequently, 13% occasionally, and 6% did not use their OS. All measured factors of usability were associated with use of OS; patients who use their OS more have a more positive opinion of the factors of usability of their OS. Comparison of these results with previous studies is almost impossible because in other studies patients with different pathologies were investigated, follow-up measurements were taken at different time points, and use was defined in various ways. In general, the rather small amount of non-use found in this study supports the conclusion that non-use of OS is not a major issue[7].

Even though non-use of OS does not seem to be a major issue, gaining insight in factors associated with the frequency of use (and non-use) is still relevant because of the high costs and efforts for the patient, medical specialist, and orthopaedic shoe technician involved in every pair of OS. We measured factors of usability within the domains effectiveness, efficiency, and satisfaction. All these factors of usability were positively associated with use. This indicates that when prescribing and evaluating OS, prescribing clinicians should not focus on the effectiveness of OS alone: factors of efficiency and satisfaction are as important as effectiveness in relation to use of OS, which is in line with previous research[12].

The considerable variation in patients' opinions of factors of usability within the groups indicates that large individual differences exist. Some patients have extremely negative opinions about some factors of usability of their OS, yet still use them frequently. Others do not use their OS, despite a very positive opinion about some factors of usability of their OS. This finding may be explained by the importance that patients attach to specific factors, a factor we did not take into account in our measurements. For example, for a patient with very severe pain, reduction of that pain may outweigh a negative opinion of the cosmetic appearance of OS: the patient will use OS every day. Whereas for another patient, the same pain reduction may still not outweigh a negative opinion of the cosmetic appearance: the patient will not use OS. Future research should take the importance that patients attach to specific factors of OS usability into

account. Clinically, this finding implies that it is essential to take all factors of usability into account for every patient and find out which factors (if any) are more important than others. The importance of structured evaluation in every individual has been stressed in recent Dutch research as well[6].

The present study has some limitations. First, we may have underestimated the rate of non-use of OS. However, characteristics of patients included in the study were comparable with all patients who were provided with a pair of OS in that period and with non-responders. Second, it could be hypothesized that patients who do not use their OS and have negative opinions of the usability of their OS are less willing to respond. To minimize this, we administered the pre-part of the questionnaire in an early stage of the process, approximately three months before delivery of OS. Not responding in that phase was not likely related to dissatisfaction with use and factors of usability of OS. Not responding to the post-part of the questionnaire was more likely to be related to dissatisfaction with use and factors of usability of OS. We therefore called these patients and were able to contact more than half of them. Only a few did not use their OS and even fewer did not respond because of dissatisfaction; all other patients did use their OS and had other reasons for not responding. Therefore, an underestimation of the rate of non-use will, in our opinion, only be a small one.

A third limitation is that we could not perform multivariate analyses. There were two reasons for that. First, MOS has two types of answer categories, which was a deliberate choice in the development of the questionnaire, during which emphasis was put on patients' preference[22]. Second, it was not possible to perform multivariate analyses on those parts of the factors of usability with similar answer categories because of the (unexpectedly) large differences in the number of patients in the three groups: more than 80% of the patients were found in one group. Because of this imbalance, it was not possible to investigate the importance of the factors of usability relative to each other.

A general limitation in the field of research regarding use and usability of OS are the three differences between all studies with regard to 1) patients, 2) time period of follow-up, and 3) definition of use, which makes comparison of results almost impossible:

First, studying patients with one specific pathology can be useful, yet may cause a problem when patients have multiple pathologies, and it is not reflective of the diversity seen in daily clinical practice. We therefore chose to include all patients, irrespective of pathology. Studying patients with one specific pathology may be relevant in specialized settings, but

information about co-morbid disorders of the patients is then essential.

Second, time point of follow-up is crucial when interpreting the results and should be chosen with care. After delivery of OS, patients need about two months to get used to OS and wearing-out problems may occur after only four months. We therefore chose to measure use after three months. Also, a second pair of OS may be delivered after five months. In that case, the usability of each pair of OS should be evaluated separately, whereas the combined frequency of use is of most interest. Still, long-term follow-up is necessary to study whether short-term use will also result in long-term use.

And third, use can be defined based on frequency, duration, environment, or task[15]. A definition based on frequency or duration is applicable for all patients, whereas a definition based on environment or task may change per individual and should always contain some information regarding the frequency or duration of use within that environment or task. We chose to define use based on frequency in order to be able to include a large group of patients. Three categories of use were defined, whereas most other studies only define two. In our opinion, a clinically relevant difference exists between these three groups. An obvious difference exists between patients who stop using OS and patients who use them. Keeping in mind that patients have to use some kind of shoes every day, a relevant difference also exists between patients who use OS occasionally and those who use them frequently. We found large differences between all three groups, which supports our opinion. This finding also indicates that important information may be missed when only two categories of use are defined and compared. In future studies, use should preferably be defined based on frequency, with a distinction between frequent use, occasional use, and non-use.

conclusions

The more positive opinion on all measured factors of usability of OS of patients who use their OS more often indicates that it is essential to take all factors of usability of OS into account when prescribing and evaluating OS. The effectiveness of OS (e.g. a change in pain after OS), the efficiency of OS (e.g. the ease of walking with OS), and the satisfaction with OS (e.g. the patient's opinion of the cosmetic appearance of OS) are all relevant in relation to use of OS.

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